# ALASKA MEDICAID PHARMACY AND THERAPEUTICS COMMITTEE

### Location of Meeting Frontier Building, 3601 C Street, Room 890/896

### FINAL MINUTES OF MEETING January 19, 2007 8:00 a.m.

#### **Committee Members Present:**

Marvin Bergeson, MD
Heidi Brainerd, MS, RPh
Amber Briggs, PharmD
Richard E. Brodsky, MD
Robert Carlson, MD (telephonic)
Jeffrey G. Demain, MD
Traci Gale, RPh (telephonic)
R. Duane Hopson, MD
Thomas K. Hunt, MD
Ronald Keller, MD
Gregory R. Polston, MD
Janice L. Stables, MSN, ANP
Trish D. White, R.Ph (telephonic)

### **Committee Members Absent:**

Kelly Conright, MD Vincent Greear, R.Ph Diane Liljegren, MD Andrzej Maciejewski, MD Sherrie D. Richey, MD Mark D. Bohrer, R.Ph

#### **Others Present:**

David Campana, RPh Melinda Sater, PharmD, First Health

#### 1. Call to Order – Chair

The meeting was called to order at 8:00 a.m.

### 2. Roll Call

A quorum was present.

### 3. Public Comment – Local Public/Local Physicians

There were no public comments.

### 4. Re-review of the Anti-emetic

There were no public testimonies.

Dr. Sater gave the First Health presentation on Anti-Emetic Medications. There are three available agents: Anzemet, Kytril and Zofran, which are available in a number of different formulations. Zofran and Kytril are currently preferred. They are all indicated for moderate and severe chemo-induced nausea and vomiting, although they have other indications. All the drugs are used for all indications. They all selectively block the 5-HT3 receptor and some block different receptor subtypes. They have similar efficacy and adverse drug reaction profiles. In December there were 94 claims: 85% for Zofran, 12.8% for Anzemet, and 3.2% for Kytril. The previous discussion was on the many different specialties that utilize this class of drugs, the lack of preference for OB patients, and the fact that there were no clinical differences between the drugs in this class. The motion was made declaring a class effect and it passed with one opposed.

# DR. HUNT MOVED TO DECLARE A CLASS EFFECT. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

### 5. Re-Review of the Anti-migraine

**Aaron Butikofer:** A representative with Merck Pharmaceuticals, Mr. Butikofer discussed Maxalt. Maxalt is indicated for the acute treatment of migraine attacks, with or without aura, in adults. It is not intended for the prophylactic therapy of migraines or for use in the management of hemiplegics or basilar migraines. The safety and effectiveness of Maxalt has not been established for cluster headaches, which is present in an older, predominately male population. It should not be given to patients with ischemic heart disease or other significant underlying cardio vascular disease, patients with uncontrolled hypertension, or within 24 hours of any ergot-type medication or another 5-HT1 agonist. Mr. Butikofer reviewed four randomized placebo controlled trials, which established the efficacy of Maxalt. Maxalt, 10 milligrams, demonstrated two-hour response rates of 67-77% and fourhour response rates of 84%. Similar trials have been conducted to assess the efficacy of Maxalt, 10 milligrams, in patients with menstrual migraines without aura. In the two menstrual migraine studies, the two-hour response rates for the treatment of moderate to severe menstrual migraine pain were 70-73% and the four-hour response rates were 82-90%. Maxalt can be given in strengths of 5 to 10 milligrams or oral disintegrating tablets. Additional doses can be given separated by two hours, not to exceed 30 milligrams in a 24-hour period. The safety of treating more than four headaches in a 30-day period has not been established. Liquid is not necessary for the administration of Maxalt MLT disintegrating tablets. Maxalt and Maxalt MLT offer fast, effective relief of migraine pain for patients. Maxalt MLT can be taken without water and is ideal for times when it is difficult for patients with migraines to swallow liquids. Maxalt MLT is the number one prescribed oral disintegrating tablet for the treatment of migraines in the United States, including Alaska. I urge you to retain Maxalt and Maxalt MLT on the Alaska Medicaid PDL.

**David Gross:** A clinical pharmacist with Pfizer, Mr. Gross discussed Relpax. The primary endpoint in the majority of the head-to-head triptan studies was the two-hour headache response. Additional endpoints were headache response and sustained pain free response. Functional response is extremely important in the largest group that suffers from migraines, which is active working adults between the ages of 30 and 50. An important clinical economic endpoint is the use of rescue medications when the first dose of the triptan fails. In a study of Relpax, 40 milligrams, versus Sumatriptan, 100 milligrams, Relpax showed a statistically significant improvement of the two-hour headache response, sustained headache response and sustained pain free response at 24 hours, as well as functional response at two hours. Mr. Gross reviewed several studies. In a comprehensive, non-industry sponsored, evidenced-

based analysis of all of the triptans, the head-to-head data shows that Relpax is the only triptan to demonstrate superiority versus Sumatriptan, 100 milligrams. The analysis also showed that significantly more patients treated with Relpax, 40 milligrams, were able to return to normal or near normal functional levels at two hours after the initial dose, allowing adults to return to productive work, thereby decreasing the absenteeism rate and the associated cost assumed by employers. The analysis also showed that fewer patients taking Relpax had to use rescue medications. The utilization of rescue medication can greatly add to the cost of treatment, as well as the development of additional side effects and resource utilization. In a study comparing the nine triptans, Relpax, 40 milligrams, was associated with both the lowest triptan cost for treatment and the lowest cost per successfully treated patient. In light of this evidence, Relpax should be added to the preferred drug list.

Jennifer Brzana: A regional medical scientist from GlaxoSmithKline, Ms. Brzana discussed Sumatriptan (Imitrex). Sumatriptan is the most widely studied triptan on the market and therefore possesses a vast library of safety and efficacy data. This data allows me to bring to your attention three pertinent points. First, it has unsurpassed pain free efficacy. A trial published in Clinical Therapeutics in 2004 showed 75% of the patients who treated their migraines early with reformulated Sumatriptan were pain free at two hours. No head-to-head trials have been conducted comparing any triptan to reformulated Sumatriptan. Second, Sumatriptan is now the most rapidly acting oral triptan available on the market. Reformulated Sumatriptan, 100-milligram tablets, has an onset of 20 minutes for moderate to severe migraines. This makes it the first oral triptan to surpass the 30-minute onset point. As always, headache relief begins as early as 10 minutes with a Sumatriptan injection and 15 minutes with a nasal spray. Third, Sumatriptan is the only triptan available in three different formulations. This allows the patient's care to be tailored to their individual migraine symptoms. Patients can use a Sumatriptan injection along with a tablet in the same 24-hour period. Utilization of this treatment strategy is unique to Sumatriptan since combining two different triptans in the same 24-hour period is contraindicated. Sumatriptan offers unsurpassed pain free rates, a rapid onset, and it is backed by the largest database of safety and efficacy data. Sumatriptan remains the gold standard for the treatment of migraine headaches.

Dr. Sater gave the First Health presentation on Anti-Migraine Medications. In the triptan class there are seven available agents. Currently, the preferred agents are Imitrex and Maxalt. Last year we grouped these agents into short and medium acting as one group and long acting as another group. The short and medium agents are Imitrex, Maxalt, Zomig, Axert and Relpax. The long acting agents are Amerge and Frova. All are indicated for the treatment of migraines, with or without aura. Imitrex injection is also indicated for cluster headaches. They have similar efficacy and adverse drug reaction profiles. There are slight differences in the receptor activity in this class. In December there were 135 claims: 3.7% for the Imitrex injection, 1.5% for Imitrex tablets, 5% for Imitrex nasal spray, 35% for Maxalt tablets, 27% for Maxalt MLT, 3.7% for Axert, 9.6% for Relpax, and everything else was 1% or less. In previous discussions, the committee decided that the agents have equal efficacy, but there is significant patient variability in response to these agents. Written statements were received from Dr. Wayne Downs and Dr. Mary Downs, which were read. Dr. Mary Downs said migraine patients vary in their response to triptans and it is best to have various options, but Relpax should be added to the PDL. Dr. Wayne Downs felt Imitrex was unique, because multiple dosage forms could be used in a single day. Relpax is very useful and frequently works when other triptans do not. Maxalt and Zomig have the advantage of the melt on the tongue tablet that does not require liquids when administering. He felt Amerge was the least effective and he rarely used it. Last year the motion was to include Imitrex, in all its dosage forms, and one other agent and the motion passed unanimously.

Dr. Polston asked how often this class of drugs was used, as opposed to the percentage prescribed.

Dr. Sater said limits for this classification was implemented in June, depending on the drug. For example, in a one-month period a patient could take nine Imitrex or six Maxalt tablets. This is more a utilization question and should probably be addressed in the DUR Program setting.

The committee discussed whether the price bids were based on a per tablet or injection basis, as opposed to the maximum number of doses allowed per month. Dr. Sater said the price per pill or injection was considered when the bids were presented for final acceptance.

Dr. Brainerd felt the issue boiled down to dosages. People who have significant nausea and vomiting often cannot take an oral medication and other forms needed to be available. The limits on this classification came about because people who need more than the limit should probably be on prophylactic medication.

Dr. Sater said other committees were more likely to choose an agent that had a broad number of available dosage forms rather than one that was just available as an oral tablet.

The committee discussed the market share of the triptans.

Dr. Hunt felt there was no clear guidance as to which should be the first drug to choose, but there was significant patient variability and response.

Dr. Demain recommended dropping the long-acting triptans from the PDL based on the market share.

Dr. Sater noted that all the dosage form for the chosen agent would be included.

MS. BRAINERD MOVED TO DECLARE A CLASS EFFECT, WITH THE INCLUSION OF ONE OR MORE AGENTS WITH DIFFERENT DOSAGE FORMS. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

### 6. Re-review of Topical Immunomodulators

**Bob Martin:** A regional scientific director with Novartis, Mr. Martin discussed Elidel. Elidel pimecrolimus cream, 1%, is indicated as a second line therapy for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children two years of age and older who have failed to respond adequately to other topical prescription treatments or when those treatments are not advisable. We have seen that the average quantity of cream used per year in the United States is 73 grams, which is less than the commonly prescribed 100-gram tube prescribed to patients. Mr. Martin discussed several trials and the safety data. Novartis is committed to working with the FDA to provide further evidence of the safety of Elidel.

**Leigh Platte:** A scientific affairs manager from Astellas Pharmaceuticals, Ms. Platte discussed Protopic. We have nearly the same indications as Elidel. Protopic is indicated as a second line therapy for the short-term use or non-continuous long-term use in patients with moderate to severe atopic determatitis for those who are non-immunocompromised or have failed therapy. It is not indicated for

children under the age of two. Dosing for children 2 to 15 is .03% and .1% for those over 16 years of age. We also have a black box warning. Our experience with this compound includes 2.1 million patients in the United States and 5.4 million patients worldwide. In our clinical trials, we looked at over 20,000 patients, including 8,000 children. We have 8,700 currently in long-term follow-up studies. In our 23 comparative clinical trials there was not a single case of malignancy. In our 12 years of clinical development, as well as post marketing surveillance, we do have a handful of malignancies. We believe Protopic is safe and effective, as well as an important tool for patients with moderate to severe atopic dermatitis.

Dr. Sater gave the First Health presentation on Topical Immunomodulators. There are two agents in this class, Elidel and Protopic. Both are currently preferred. They are both indicated for the treatment of atopic dermatitis, although they are used for other indications as well. Both drugs have similar efficacy and adverse drug reaction profiles. Elidel is a cream. Protopic is an ointment. There is very little systemic absorption of these drugs. Both carry pediatric indications, although Protopic has a lower strength for the pediatric indications. In December, there were 83 claims for the drugs in this class: 73.5% for Elidel and 26.5% for Protopic. In previous discussions, the committee felt that there was a role for each of these drugs. The importance of having both drugs available for pediatrics was discussed. The motion was made that both should be included on the PDL and it passed unanimously.

Dr. Demain felt both Elidel and Protopic should be included on the PDL. Elidel is more preferred in pediatrics, because it does not sting as much.

DR. DEMAIN MOVED TO INCLUDE BOTH ELIDEL AND PROTOPIC, IN THEIR DOSAGE FORMS, ON THE PDL. SECONDED BY DR. KELLER. THE MOTION PASSED UNANIMOUSLY.

### 7. Re-review of Urinary Track Antispasmodics

**Bob Martin:** A regional scientist from Novartis, Mr. Martin discussed Enablex. Enablex is available in 7.5- and 15-milligram dosage forms. It is typically indicated for over active bladder treatment. There are five known subtypes of muscarinic receptors throughout the body, M1 through M5. Typically, M-2 and M-3 are associated with the bladder. Therapies that selectively target the M-3 receptors are attractive for two reasons. They act directly on the specific receptors that control the detrusor muscle contractility and they largely spare the muscarinic receptors in the heart and brain. They are not associated with cardiac and CNS-adverse events, which are contrary to important safety issues with the non-selective OAB drugs. Mr. Martin discussed several trials on Enablex. The most common adverse events reported are dry mouth and constipation, however these infrequently result in treatment discontinuation. The present two-year results show that Enablex is well tolerated, effective and has no significant safety concerns in the long-term treatment of OAB. The starting dose of 7.5 milligrams once daily is well tolerated and provides significant improvements in symptoms for patients with the greatest drug sensitivity, with the option to increase to 15 milligrams if additional efficacy is required.

**Leigh Platte:** A scientific affairs manager from Astellas Pharmaceuticals, Ms. Platte discussed VESIcare (Solifenacin). In our registration trials of over 1,800 people, Solifenacin, 5 milligrams, was able to achieve a 51% dry rate among patients with only an 11% rate of dry mouth, which is the most common side effect in this classification of drugs. In our long-term studies, 81% of patients were still on Solifenacin at the end of one calendar year. Ms. Platte discussed several trials on Solifenacin. In the

Venus trial, Solifenacin was statistically significant over placebo in reducing the number of urgency episodes per 24 hours. The secondary endpoint was reducing the number of episodes of incontinence and it was also statistically significant. Solifenacin should remain on the PDL, because it is safe and effective for the majority of patients.

David Gross: A clinical education manager with Pfizer, Mr. Gross discussed Detrol and Detrol LA. When you evaluate evidence in head-to-head clinical trials, no other OAB medication has been able to show superiority to Detrol LA when evaluating primary efficacy endpoints. Mr. Gross discussed several trials on Detrol and Detrol LA. For elderly patients, the side effects of dry mouth, dizziness and constipation can be very troublesome so adherence to this classification of drugs is not great. Detrol showed significantly lower rates of dry mouth and constipation. In six of the seven studies comparing Detrol LA to Oxybutynin, there were lower dropout rates in patients using Detrol and this reached statistical significance in four of the seven studies. While the clinical trial discontinuation rate is valuable, it is interesting to look at real world data. We know that adherence is troublesome in all drug categories, but it is especially troublesome in this category. Adherence literature in the field revealed a total of six published claims analyses comparing Detrol LA to Oxybutynin and one focused solely on Medicaid patients. The results of these analyses consistently reported that overall compliance rates tend to be low, but there were consistently higher persistence rates with Detrol when compared with Oxybutynin. In light of the effectiveness and tolerability data, as well as the important clinical trial and prescription claims data, Detrol LA should remain on the PDL.

Dr. Sater gave the First Health presentation on Urinary Track Antispasmodics. There are nine available products. Detrol LA, VESIcare, Enablex and the generic Oxybutynin are preferred. The agents all have similar efficacy, although the adverse drug reaction profiles differ. Patients better tolerate the newer agents. In December, there were 311 claims: 55.3% for Detrol LA, 13.8 for Oxybutynin generic; 10.6% for Ditropan XL, 8.4% for VESIcare, 6.1% for Enablex, 2.9% for Oxytrol, .3% for Sanctura and .3% for Ditropan brand. In previous discussions, similar efficacy of all agents was discussed, although Detrol LA was definitely favored for its adverse drug reaction profile and patient tolerability. The expert opinion is provided in the packet of information. Detrol LA is definitely the choice for providers in this area. Last year the motion was to include Detrol LA and whatever others fell out in the bidding process and that motion passed unanimously.

# DR. HUNT MOVED TO INCLUDE DETROL LA AND THE OTHER MEDICATIONS THAT FELL OUT IN THE BIDDING PROCESS. SECONDED BY DR. POLSTON. MOTION PASSED UNANIMOUSLY.

#### 8. Re-review of Proton Pump Inhibitors

**Doug Stogsdill:** A regional scientific manager with AstraZeneca, Mr. Stogsdill discussed Esomeprazole (Nexium). There are several ways to compare proton pump inhibitors. Since all proton pump inhibitors suppress gastric acid the same way, the 24-hour PH is an ideal method. In 11 different comparative studies, Esomeprazole provided greater intergastric PH or acid control than Lansoprazole, Pantoprazole, Rabeprazole or Omeprazole delayed released capsules. Another way to judge efficacy is to look at healing of erosions. Erosive esophagitis is estimated to be present in approximately 30% of all GERD patients. It has a general population prevalence of about 2-7%. Esomeprazole is the first proton pump inhibitor to demonstrate a statistically significant difference in healing when compared to any other proton pump inhibitor. Several head-to-head trials have examined the healing rates of

Esomeprazole versus the other agents. Esomeprazole, 40 milligrams, had consistently higher healing rates across all grades, as well as in patients who had more severe disease. Because the prevalence and severity of erosive disease cannot be determined except through diagnostic testing, it is reasonable that a treatment that is reliable in healing all grades of erosive disease be considered for patients with clinical symptoms of GERD. Nexium also has some new indications. One is the reduction of the occurrence of gastric ulcers associated with continuous non-steroidal therapy in patients at risk for developing gastric ulcers. It also has an indication for the long-term treatment of pathological hypersecretory conditions and for short-term treatment of GERD in adolescent patients age 12-17. For patients who have difficulty swallowing the capsules, Esomeprazole can be opened and put in applesauce. The pellets are also stable in other media. Esomeprazole pellets can be suspended in water and given through a nasal gastric tube. It is now available in a delayed released oral suspension that can be administered orally or via a nasal gastric tube, as well as an IV formulation for short-term treatment in GERD patients. Nexium should remain on the Alaska PDL.

**Pheophilus Glover:** A regional manager for TAP Pharmaceuticals, Mr. Glover discussed Prevacid. When reviewing a PPI, one must look at the degree of acid suppression and the length of time. We have very strong data on the healing rates of raising and maintaining the PH. We have efficacy data with patients with erosive esophagitis. We also have strong maintenance data on the prevention of reoccurrence for patients with healed erosive esophagitis. When looking at FDA approved indications, Prevacid has the most FDA indications. It is indicated for pediatrics, ages 1 to 11; adolescents, ages 11 to 17; as well as prevention on inset induced ulcers; healing and maintenance of various ulcers; and symptom relief associated with GERD. Prevacid has multiple administration options. It is available as an oral capsule, which can be taken orally or sprinkled on soft foods or in juices. It can be given via a nasal gastric tube. It has an oral suspension and an IV formulation. One of our newest formulations is Prevacid solutabs. It is currently the first and only orally disintegrating proton pump inhibitor available on the market. When placed on the tongue, it dissolves in less than 60 seconds. It can also be taken with or without water. The Prevacid solutab is bio-equivalent to the capsule, so there is no dosage adjustment necessary and it has the same indications. The solutab can be given via an oral syringe or a nasal gastric tube. This is helpful especially in the pediatric population, because a parent can dissolve it in as little as 5cc's of water while insuring that the patient receives the complete dose. It is also a strawberry flavored product. Alaska Medicaid should continue to have Prevacid capsules available and Prevacid solutabs should be added for patients who need variability in formulations.

Dr. Sater gave the First Health presentation on Proton Pump Inhibitors. There are five available agents, six brands. Nexium and Prevacid are currently preferred. There are varied FDA indications for the agents, but all the agents are used for all the indications. Their adverse drug reaction profiles and efficacy are similar. In December there were 2,555 claims: 37% for Nexium, 31% for Prevacid capsules, 3.2% for Prevacid rapid dissolving tablets, 5% for Prevacid granules for suspension, 21% for generic Omeprazole, 1% for Aciphex, and a negligible number of claims for Protonix, Zegerid and Prilosec. In previous discussions, the agents were deemed to have similar efficacy. There was some discussion on pediatric use and having Prevacid on the PDL for that purpose. The difficulty associated with frequent changes to the preferred agents in this class was also discussed. A class effect was declared and it passed with one opposed.

Dr. Demain pointed out that Omeprazole generic was only available in the 10 and 20-milligram strengths. How would a pharmacy handle a prescription for Omeprazole, 40-milligram?

Dr. Sater said that would depend on the pharmacy. Some would use two 20-milligram tablets, some would substitute and some would call the doctor. However, generic Omeprazole is not preferred.

Ms. White pointed out that it was difficult for pharmacies to carry a wide variety of PPIs. She would like to see Omeprazole generic added to the PDL, because it is on other formularies.

Dr. Sater said prices were monitored very carefully. As soon as a generic became remotely cost effective, it is added to the PDL.

Dr. Bergeson pointed out that a dissolvable formulation was needed for patients who needed to have the drug administered by gastric tubes.

Dr. Keller felt they needed to have a formulation for children.

# DR. KELLER MOVED THAT THIS IS A CLASS EFFECT. SECONDED BY DR. HUNT. THE MOTION PASSED UNANIMOUSLY.

#### 8. Re-review of Anti-Tumor Necorsis

Carrie Johnson: A PharmD from the University of Washington, Ms. Johnson discussed Enbrel. Enbrel is unique as the only fully human soluble TNF receptor. Enbrel has the broadest coverage of indications crossing both dermatology and rheumatology. It is indicated for RA and ankylosing spondylitis, psoriatic arthritis, psoriases and pediatric patients for JRA. The pediatric indication differentiates Enbrel from the others. It has been studied in patients down to two years of age. We have sustained clinical efficacy and safety data out to four years in patients with JRA. Enbrel has demonstrated sustained clinical responses out to nine years in patients with RA at a stable dose. Enbrel, in combination with Methotrexate, has shown three years of sustained halting of radiographic progression in patients with RA. Enbrel provides predictable dosing. It does not cause the formation of neutralizing antibodies, which may affect efficacy and maintenance of response over time. There is no labeling allowing for increase in dose. Unlike other TNF antagonists, Enbrel has no black box warnings. The only adverse events, seen more often in treated versus untreated patients in clinical trials, has been injection site reactions. No testing, pre- or post-initiation or routine laboratory monitoring specific to Enbrel, is required. Rates of serious adverse events and serious infection over the past nine years have remained low and not significantly differently from Methotrexate or placebo. In terms PDL placement, the acceptance record for Etanercept is unparalleled. Of the 23 state Medicaid programs that reviewed the anti-TNF category all have placed Etanercept on the PDL. Enbrel is available in 50-milligram pre-filled syringes, 25- and 50-milligram vials and a 50-milligram pre-filled auto injector called SureClick. Etanercept is unique among TFN antagonists. It has over 14 years of collective clinical trial experience in over 400,000 patients worldwide, across indications. Rates of serious adverse events have remained low and stable over time. It has a pediatric indication, predictable dosing, no black box warnings, and published long-term clinical, efficacy and safety data.

**Marcie Nakanischi:** From Abbott Laboratories, Ms. Nakanischi discussed Humira. Humira is the first fully human monoclonal antibody directed specifically against TNF-a, the cytokine responsible for the inflammation of rheumatoid arthritis. Humira binds with high affinity and specificity to TNF-a and neutralizes the biological function of TNF, thereby reducing the inflammatory process and inhibiting disease progression. Humira has been on the market for just over three years, but has over six years of

clinical trial efficacy data. In rheumatoid arthritis, Humira provides a rapid onset of action, significantly reducing the signs and symptoms of RA within one week, significantly improving physical function and inhibiting radiographic progression of disease, both erosions and joint space narrowing. It is also used to reduce signs and symptoms of active arthritis in patients with psoriatic arthritis. Humira can be used alone or in combination with Methotrexate or other DMARDs as it has convenient dosing for the patient as a subcutaneous injection once every other week. Humira is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. As of April 2005, Humira had over 10,000 patients in global clinical trials with the serious infections, tuberculosis and lymphoma rates were well within the range of other documented anti-TNF and biologic naive RA patient incident data. Humira has filed for an indication for the treatment of Crohn's disease and has been granted an expedited review by the FDA. There is an abundance of both clinical and trial efficacy and safety data with Humira being the third anti-TNS to market. It also has the benefit and ease of administration as an every other week subcutaneous injection.

Dr. Sater gave the First Health presentation on Anti-Tumor Necrosis. There are three available agents, Enbrel, Kineret and Humira. They have slightly different mechanisms. Although the adverse drug reaction profiles are similar, the dosing regimens are completely different. They have different indications. In December there were 40 claims: 77.5% for Enbrel, and 22.5% for Humira. Last year there was significant discussion about these agents being prescribed by primary care providers due to the unavailability of rheumatologists in Alaska. Dr. Ferrucci feels that Enbrel should be the first line agent, but would prefer that all agents were available. She feels Enbrel is safer and better tolerated, although it might be slightly less effective than Humira. She also felt a step-edit, where a patient had to fail Enbrel before moving on to another agent, was reasonable, but probably unnecessary. All three agents are currently preferred. The motion last year was that all the agents should be available and it passed unanimously.

Dr. Hunt asked what the cost implications would be for a step-edit and whether one drug would be preferred.

Dr. Sater said all agents could be preferred, but an additional step could be added to how the claims were processed.

Dr. Demain said most patients with RA, after some period of time, need to move on to a different product to get recapture. He felt Enbrel and Humira should be preferred, because the drugs are probably equally efficacious, but have unique characteristics.

# DR. DEMAIN MOVED TO INCLUDE ENBREL AND HUMIRA ON THE PDL. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

#### 10. Re-review of H2RA

There were no public testimonies.

Dr. Sater gave the First Health review of H2RA. There are four agents in this class, all of which are available generically. Ranitidine and Famotidine are currently preferred agents. They have similar indications and efficacy. The drug interaction profile of Cimetidine was discussed last year. There is nothing new in this class. In December there were 587 claims: 67% for Ranitidine, 16.5% for

Famotidine, 13.6% for Zantac syrup, 1.4% for Pepcid suspension, 1.2% for Cimetidine, and the other Pepcid and Zantac brands had a few negligible claims. The motion last year was to declare a class effect with a corollary motion that Cimetidine not be preferred and both passed unanimously.

Dr. Hunt said it was his understanding that most of these drugs were available over-the-counter and Medicaid did not pay for them.

Dr. Sater said Medicaid paid for the prescription products, but not for the over-the-counter products.

Dr. Demain felt it was important to have a suspension or syrup formulation for pediatric patients.

DR. DEMAIN MOVED TO DECLARE A CLASS EFFECT, NOT TO PREFER CIMETIDINE DUE TO ITS DRUG INTERACTIONS, AND TO INCLUDE A SYRUP OR SUSPENSION FORMULATION FOR PEDIATRICS. SECONDED BY DR. KELLER. MOTION PASSED UNANIMOUSLY.

### 11. Final Comments by Chair or Other Members

Dr. Brodsky introduced Ed Bako, who would be working with Mr. Campana on the DUR Program and quality assurance for the Medicaid Pharmacy Program.

Mr. Campana said Mark Bohrer, a pharmacist with Fred Myer's, was appointed to the board. A dentist still needs to be appointed and hopefully will join the committee at the next meeting.

### **13.** Meeting Minutes

The board reviewed the meeting minutes of November 17, 2006. Mr. Campana noted several changes.

# DR. HUNT MOVED TO APPROVE THE MEETING MINUTES OF NOVEMBER 17, 2006, AS AMENDED. SECONDED BY DR. BERGESON. MOTION PASSED UNANIMOUSLY.

Mr. Campana reviewed what would be discussed at the next meeting, which was scheduled for February 16, 2007.

Dr. Sater did not review the changes made to the PDL during this meeting. The determinations will be made after the new bids are received next month. The results of the January and February meeting will be available at the April meeting.

# DR. HUNT MOVED TO ADJOURN THE MEETING. SECONDED BY DR. DEMAIN. MOTION PASSED UNANIMOUSLY.

The meeting adjourned at 10:22 a.m.